| UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK x | CCCSDNY |
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| UNITED STATES OF AMERICA; the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSE, TEXAS, VIRGINIA, WASHINGTON, and WISCONSIN; the DISTRICT OF COLUMBIA, the CITY OF CHICAGO, and the CITY OF NEW YORK; <i>ex rel.</i> , CHARLES ARNSTEIN AND HOSSAM SENOUSY, | DOCUMENT ELECTRONICALLY FILED DOC#: POSSINE |
| Plaintiffs and Relators, | |
| -against- | 13 Civ. 3702 (CM) |

TEVA PHARMACEUTICALS USA, INC., TEVA NEUROSCIENCE, INC., and TEVA SALES AND MARKETING, INC.

Defendants.

ORDER DENYING DEFENDANTS' MOTION FOR CERTIFICATION OF AN INTERLOCUTORY APPEAL PURSUANT TO 28 U.S.C. § 1292(b)

McMahon, C.J.:

Defendants ("Teva") move for leave to appeal the Court's denial of their motion for summary judgment, pursuant to 28 U.S.C. § 1292(b). (Dkt. No. 170.) As part of the order denying summary judgment, the Court rejected Teva's argument that Relators had failed to meet their burden of production on causation, finding that "Relators need not show that any speaker

increased his or her prescription writing . . . in response to Teva's alleged kickbacks." (Dkt. No. 163 at 47.)

Teva now seeks certification of a single issue for appeal: a "relator's burden of proof in a False Claims Act ["FCA"] action alleging that a defendant 'cause[d] to be presented'" false claims resulting from a violation of the Anti-Kickback Statute ("AKS"). (Defs.' Mem. of Law in Supp. of Mot. To Certify Interlocutory Appeal and To Postpone Trial Pending Appeal ("Teva Br."), Dkt. No. 171 at 1.)

For the reasons that follow, Teva's motion is DENIED.

28 U.S.C. § 1292(b) provides, in relevant part:

When a district judge, in making in a civil action an order not otherwise appealable under this section, shall be of the opinion that such order involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation, he shall so state in writing in such order.

Id. In deciding whether to certify an interlocutory appeal, "The court must determine whether all three of the statutory requirements are satisfied[.]" In re Air Crash at Georgetown, Guy. on July 30, 2011, 33 F. Supp. 3d 139, 155 (E.D.N.Y. 2014). Even if all three factors are met, however, "district court judges retain unfettered discretion to deny certification of an order for interlocutory appeal." Nat'l Asbestos Workers Med. Fund v. Philip Morris, Inc., 71 F. Supp. 2d 139, 162 (E.D.N.Y. 1999). The Second Circuit has also cautioned that "use of this certification procedure should be strictly limited because only 'exceptional circumstances will justify a departure from the basic policy of postponing appellate review until after the entry of a final judgment." In re Flor, 79 F.3d 281, 284 (2d Cir. 1996) (quoting Klinghoffer v. S.N.C. Achille Lauro, 921 F.2d 21, 25 (2d Cir. 1990)).

Both parties agree that the causation question is controlling; Teva necessarily would have prevailed on its summary judgment motion had Relators failed to meet their burden of production on causation. (See Teva Br. at 1; see generally Pls.-Relators' Mem. of Law in Opp. to Defs.' Mot. To Certify for Interlocutory Appeal and To Postpone Trial Pending Appeal ("Rels. Opp."), Dkt. No. 178.)

The parties disagree, however, on whether "there is substantial ground for difference of opinion." (Teva Br. at 2–7; Rels. Opp. at 7–18.) This requirement is ordinarily met "when there is conflicting authority on the issue" or the issue is "difficult and of first impression in this Circuit." *In re Lehman Bros. Holdings Inc.*, No. 08-br-13555, 2010 WL 10078354, at *6 (S.D.N.Y. Sept. 23, 2010) (internal quotation omitted). At the same time, "the mere presence of a disputed issue that is a question of first impression, standing alone, is insufficient to demonstrate a substantial ground for difference of opinion." *In re Flor*, 79 F.3d at 284. "Rather," the district court must "analyze the strength of the arguments in opposition to the challenged ruling when deciding whether the issue for appeal is truly one on which there is a *substantial* ground for dispute." *Id.* (emphasis in original) (internal quotation omitted).

Before applying this standard, it must be said that, in connection with its motion for summary judgment, Teva either did not raise, or raised only in reply, the arguments it now fulsomely advances in support of the instant motion.

In its opening brief, Teva focused on the causation standard under the AKS, which renders false as a matter of law "a claim that includes items or services *resulting from* a violation of this section." 42 U.S.C. § 1320a-7b(g) (emphasis added). It was not until Teva filed its reply brief that it first mentioned that Relators *also* failed to meet the separate causation standard under the FCA, 31 U.S.C. § 3729(a)(1)(A). According to Teva, the FCA requires "but for" causation

in cases where the defendant "causes [a false claim] to be presented" to the Government.

Despite the fact that the argument was first raised in reply, the Court carefully considered and rejected that argument, finding no support for this interpretation in any FCA case predicated on an AKS violation, and found that such an interpretation would undermine the legislative purpose behind the 2010 amendments to the AKS. (Dkt. No. 163 at 52–54.)

Teva "does not even attempt to argue that conflicting authority exists on this question, and points to no case in which another court has held that" the AKS requires "but for" causation in "cause[] to be presented" cases. *Moton v. Maplebear Inc.*, No. 15-cv-8879, 2017 WL 5515943, at *3 (S.D.N.Y. Mar. 20, 2017).

Instead, Teva argues that the law is "unsettled." (Teva Br. at 7.) True, the 2010 AKS amendments are of relatively recent vintage; the dearth of pertinent case law suggests that the interplay between the two statutes is something of a novel question. However, "novelty alone does not difficulty make." *Dev. Specialists, Inc. v. Akin Gump Strauss Hauer & Feld LLP*, No. 11-cv-5968, 2012 WL 2952929, at *7 (S.D.N.Y. July 18, 2012). Instead, the cases to consider this issue—and Teva has drawn the Court's attention to no others—have uniformly failed to require "but for" causation in AKS cases. *United States ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89, 98 (3d Cir. 2018) (*Greenfield*); *Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019).

In seeking certification for an interlocutory appeal, Teva raises a second argument, one that did not appear at all in the summary judgment papers. *See Moton*, 2017 WL 5515943, at *4 (denying interlocutory appeal where plaintiff "failed to raise [an] argument, even obliquely," such that "it was not addressed in the Court's . . . order"); *see also N.Y.C. Health & Hosps. Corp. v Blum*, 678 F.2d 392, 396–97 (2d Cir. 1982) ("the section allows interlocutory appeal of

orders—not interlocutory appeal of issues"). Since this Court had no opportunity to consider Teva's argument in the first instance, that alone is reason to deny certification.

Teva's new argument is that false certification—the relators' theory in *Greenfield*, 880 F.3d 89—is one theory of liability in AKS/FCA cases, while subsection (g)'s "resulting from" language is a separate and entirely independent theory of liability. (Teva Br. at 4.) Under Teva's theory, subsection (g)'s "resulting from" language was irrelevant in cases like *Greenfield*, which proceeded on a theory of false certification. (*Id.*) The *Greenfield* court's interpretation of "resulting from" was therefore unnecessary dicta.

That being so, Teva contends the Court instead should look to *Burrage v. United States*, 571 U.S. 204 (2014), in order to determine the meaning of the phrase "resulting from." And in *Burrage*, of course, the U.S. Supreme Court read the language "results from" in the Controlled Substances Act (a different statute altogether) to require "but for" causation, *id.* at 210–11. (Teva Br. at 5–6.)

Teva cites no case (or even law review article) that recognizes two separate theories of liability in AKS/FCA cases: false certification liability and subsection (g) "resulting from" liability. (See Defs.' Reply Mem. of Law in Supp. of Their Mot. to Certify Interlocutory Appeal and to Postpone Trial Pending Appeal, Dkt. No. 179-1 at 10 ("If the Second Circuit recognizes that false certification and Section 1320a-7b(g) are alternative theories of liability, then it will recognize that Greenfield's interpretation of 'resulting from' was unnecessary and incorrect.") (emphasis added).) Moreover, Congress passed the 2010 amendments to expand AKS enforcement; Congress could not rationally have sought to accomplish this by raising the legal hurdles that relators must clear—or by enacting standards more stringent than the criminal provisions of the same statute. It seems clear to this Court that subsection (g) obviated the need

for the false certification theory in AKS cases, replacing it with the far less arduous "resulting from" standard. *See United States v. Catholic Health Initiatives*, 312 F. Supp. 3d 584, 594 (S.D. Tex. 2018). As Relators have pointed out, the *Greenfield* court itself took these legislative goals into account when it considered if its interpretation of the phrase "resulting from" was "consistent with how the Supreme Court has construed those words in other statutes, most notably the Controlled Substances Act." 880 F.3d 89 at 96 (citing *Burrage*, 571 U.S. at 210–11). Examining statements of legislative intent for both the AKS' criminal and civil provisions, as well as for the FCA, the Third Circuit concluded that application of the "but for" standard "would lead to results not intended by Congress." *Id.* at 97. Ultimately, courts are in near-universal agreement that the 2010 amendments demonstrate a significant Congressional commitment to enforcing the Anti-Kickback Statute, regardless of who ultimately submits the claims to the Government.

Even if Teva had succeeded in demonstrating a "substantial ground for difference of opinion," however, its motion would still fail because the Court finds that "the main effect of granting [Teva's] motion would be to materially delay, rather than materially advance, the ultimate termination of the litigation." *Picard v Katz*, 466 B.R. 208, 210 (S.D.N.Y. 2012); *see also In re Facebook, Inc., IPO Sec. & Derivative Litig.*, 986 F. Supp. 2d 524, 531 (S.D.N.Y. 2014) ("obtaining reversal . . . will *always* contain the possibility of a dismissal and is not an exceptional circumstance that justif[ies] a departure from the basic policy of postponing appellate review until after the entry of a final judgment") (emphasis in original) (internal quotation omitted). The parties have already submitted their joint proposed pretrial order, and the Court is looking for a trial date. The Court agrees with Relators that "the interests of judicial

economy are served by having the parties present all of their evidence at trial (including all evidence regarding causation)." (Rels. Opp. at 19.)

For the reasons stated above, Teva's motion for certification of an interlocutory appeal and to postpone trial is **DENIED**.

The Clerk of Court is respectfully requested to close the motion at Docket Number 170.

Dated: April <u>//</u>, 2019

Chief Judge

BY ECF TO ALL PARTIES